

ZETEZE TABLET

Ezetimibe (10 mg)

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Please read this information carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information may have changed. You should also read any information provided with other medicines you are currently taking.

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

What ZETEZE TABLET is used for

ZETEZE TABLET contains 10 mg of ezetimibe as the active ingredient.

- **ZETEZE TABLET** is a cholesterol-lowering medicine.
- **ZETEZE TABLET** is for patients whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.
- **ZETEZE TABLET** reduces elevated total-cholesterol, LDL (bad) cholesterol and triglycerides and increases HDL (good) cholesterol.
- **ZETEZE TABLET** may be taken with other cholesterol-lowering medicines known as statins or alone, in addition to diet.
- **ZETEZE TABLET** may be taken with fenofibrate, another cholesterol-lowering medicine, in addition to diet.

How ZETEZE TABLET works

- **ZETEZE TABLET** works by decreasing the absorption of cholesterol in the small intestine. Statins and fenofibrate lower cholesterol in a different way; they work in the liver.
- **ZETEZE TABLET** adds to the cholesterol-lowering effect of statins and fenofibrate.

Why has my doctor prescribed ZETEZE TABLET?

Your doctor has prescribed **ZETEZE TABLET** to reduce the amount of cholesterol and triglycerides in your blood. Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL and HDL cholesterol.

LDL cholesterol is often called “bad” cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

HDL cholesterol is often called “good” cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

How can high cholesterol be treated? High cholesterol can be treated in two main ways:

Lifestyle Changes – including a cholesterol-lowering diet, increased physical activity, and weight management.

Medication – Cholesterol-lowering medicines are used together with lifestyle changes to help lower cholesterol. Your doctor has prescribed

ZETEZE TABLET to help lower your cholesterol.

Before you use ZETEZE TABLET

It is important that you continue taking **ZETEZE TABLET** daily as prescribed by your doctor.

Even if you are taking medication to treat high cholesterol, it is important to have your cholesterol measured regularly. You should also know your cholesterol levels and goals.

Use in elderly

No special precautions.

Use in children

ZETEZE TABLET is not recommended in children under age 10.

- When you must not use it

Patients who are hypersensitive (allergic) to Ezetimibe or any of its ingredients should not take **ZETEZE TABLET**

- Before you start to use it

Tell your doctor about:

Pregnancy: If you are pregnant or plan to become pregnant, Ezetimibe may not be right for you.

Breast-feeding: If you are breast-feeding, Ezetimibe may be passed in your milk to your baby.

Medical Problems or Allergies: Talk about any medical problems (including liver disease or liver problems) or allergies you have now or have had in the past.

ZETEZE TABLET contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **ZETEZE TABLET**.

- Taking other medicines

You should always tell your doctor about all drugs that you are taking or

plan to take, including those obtained without a prescription.

In particular, tell your doctor if you are taking medicine(s) with any of the following active ingredients:

- cyclosporin (often used in organ transplant patients)
- medicines with an active ingredient to prevent blood clots, such as warfarin or fluindione (anticoagulants)
- cholestyramine (also used to lower cholesterol), because it affects the way ezetimibe works
- fibrates (also used to lower cholesterol)

How to use ZETEZE TABLET

- How much to use

Take one 10 mg tablet by mouth each day, at any time of day.

- When to use it

- Take **ZETEZE TABLET** with or without food.
- Your doctor may let you take **ZETEZE TABLET** along with other medicines, known as statins, or with another medicine known as fenofibrate, to help you better control your cholesterol.
- If you are taking a statin or fenofibrate, ezetimibe can be taken at the same time as the other medicine.
- If your doctor has prescribed ezetimibe along with cholestyramine (a bile acid sequestrant) or any other bile acid sequestrant, **ZETEZE TABLET** should be taken at least 2 hours before or 4 hours after taking the bile acid sequestrant.

- How long to use it

Continue taking your cholesterol-lowering medicines unless your doctor tells you to stop.

- If you forget to use it

Try to take **ZETEZE TABLET** as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet daily.

- If you take too much (overdose)

Take **ZETEZE TABLET** only as prescribed for you. If you take more **ZETEZE TABLET** than you were prescribed, contact your doctor or pharmacist.

While you are using ZETEZE TABLET

- Things you must do

- **ZETEZE TABLET** should be taken as directed by your health care provider.
- Talk about any other medicines that you are taking or plan to take. Include those you can get without a prescription.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not take **ZETEZE TABLET** if you are hypersensitive (allergic) to **ZETEZE TABLET** or any of its ingredients.
- Do not give **ZETEZE TABLET** to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Can I drive or operate machinery while using ZETEZE TABLET?

There have been side effects reported with ezetimibe that may affect your ability to drive or operate machinery. Individual responses to **ZETEZE TABLET** may vary. (See **Side effects**)

Side effects

Ezetimibe is generally well tolerated. The side effects are usually mild. Side effects generally do not cause patients to stop taking **ZETEZE TABLET**.

When used alone, the following side effects were reported:

Common; abdominal pain; diarrhoea; flatulence; feeling tired.

Uncommon: elevations in some laboratory blood tests of liver (transaminases) or muscle (CK) function; cough; indigestion;

heartburn; nausea; joint pain; muscle spasms; neck pain; decreased appetite, pain, chest pain, hot flush; high blood pressure.

Additionally, when used with a statin, the following side effects were reported:

Common: elevations in some laboratory blood tests of liver function (transaminases); headache; muscle pain.

Uncommon: tingling sensation; dry mouth; itching; rash; hives; back pain; muscle weakness; pain in arms and legs; unusual tiredness or weakness; swelling, especially in the hands and feet.

When used with fenofibrate, the following side effect was reported:

Common: abdominal pain.

Additionally, the following side effects have been reported in general use: allergic reactions (which may require treatment right away) including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing, rash, and hives; raised red rash, sometimes with target-shaped lesions; muscle aches; unusual tiredness or weakness; alterations in some laboratory blood tests; liver problems; inflammation of the pancreas constipation; dizziness; tingling sensation; depression; gallstones; and inflammation of the gallbladder.

Contact your doctor promptly if you experience unexplained muscle pain, tenderness, or weakness while taking ezetimibe.

This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage.

Talk to your doctor anytime you have a medical problem you think may be related to ezetimibe.

If you are prescribed ezetimibe with a statin, your healthcare professional may want to conduct routine blood tests to check your liver function

before and after starting treatment.

You may report any side effects or adverse reaction directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → reporting).

How can I learn more about Ezetimibe and my condition?
You may obtain further information from your doctor or pharmacist.

Storage and disposal of ZETEZE TABLET

- Storage

Do not store above 30°C.

Keep ZETEZE TABLET and all medications away from children.

- Disposal

How long should I keep my medicine?

Do not use this medicine after the date shown following EX (or EXP) on the container..

Product description

ZETEZE TABLET are white to off white capsule shaped uncoated tablets with 'E 10' debossed on one side and plain on other side.

- Ingredients

Active ingredient: Ezetimibe

Inactive ingredients: Lactose monohydrate, povidone, croscarmellose sodium, sodium lauryl sulphate, pregelatinised starch, magnesium stearate.

- MAL number:

MAL16045036AZ

Product Manufacturer

SUN PHARMACEUTICAL INDUSTRIES LIMITED

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Product Registration Holder:

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